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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,775	08/06/2003	Akihiro Shimase	KAS-189	6851

7590 07/29/2005  
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EXAMINER

NGHIEM, MICHAEL P

ART UNIT PAPER NUMBER

2863

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/634,775

Applicant(s)

SHIMASE ET AL.

Examiner

Michael P. Nghiem

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 7-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 3, 8-10, 13, 14 and 16-23 is/are allowed.
- 6) ☒ Claim(s) 4 and 7 is/are rejected.
- 7) ☒ Claim(s) 11 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

The Amendment filed on May 16, 2005 has been acknowledged.

### ***Withdrawal of Allowability***

The indicated allowability of claims 4 and 7 is withdrawn in view of the newly discovered reference(s) to Takeda et al. (US 5,540,081). Rejections based on the newly cited reference(s) follow.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gherson et al. (US 6,022,747) in view of Takeda et al. (US 5,540,081).

Regarding claims 4 and 7, Gherson et al. discloses a sample dispensing apparatus (10) and method (Fig. 1) comprising:

- a probe (12) for sucking and ejecting a sample (Fig. 1), a dispensing syringe (38) for generating a pressure in said probe to suck and eject the sample (Fig. 1), a dispensing flow passage (passage comprises 20, 30) connecting said probe and said dispensing syringe (Fig. 1), and a control unit (14) for controlling sucking and ejection operations of the sample (Fig. 1), said apparatus further comprising:

- at least one pressure sensor (40) for detecting a pressure in said dispensing flow passage (Fig. 1);

- pressure value storing means (computer memory storing output values of 40) for time-serially storing output values of said pressure sensor (Abstract, lines 4-6, column 6, lines 2-4) during an operation of dispensing the sample (column 6, line 67 – column 7, line 3);

- storage means (computer memory for storing reference values) for storing a reference database consisted of time-serial output values of said pressure sensor (Abstract, lines 6-8), which are obtained when the sample is normally sucked or ejected by said probe (Abstract, line 7);

- determining means (42) for carrying out multi-variable analysis of both said reference database and comparison data created based on the output values of said pressure sensor time-serially stored in said pressure value storing means (column 7, lines 45-48), and for determining the presence or absence of an abnormality in the dispensing operation of the sample based on an analysis result (Abstract, lines 17-20, column 7, lines 48-61).

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However, regarding claims 4 and 7, Gherson et al. does not disclose discrimination means for, when the abnormality of sample dispensing is detected, comparing a pressure value immediately before the end of the sample sucking operation with a preset threshold, and for discriminating a cause of the dispensing abnormality.

Nevertheless, Takeda et al. discloses discrimination means (discriminating circuits, Abstract, lines 8-9) for the purpose of detecting a blood clot alarm condition (Abstract, lines 11-15).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Gherson et al. with discrimination means as disclosed by Takeda et al. for the purpose of detecting a blood clot condition.

### ***Allowable Subject Matter***

Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2, 3, 8-10, 13, 14, and 16-23 are allowed.

### ***Reasons For Allowance***

The combination as claimed wherein determining means for determining an abnormality of sample dispensing by comparing the Mahalanobis distance calculated from both comparison data prepared based on the output values of said pressure sensor time-serially stored in said pressure value storing means and said reference database, with a preset threshold (claims 2, 23) or after washing the interior of said dispensing flow passage including said sample probe, dispensing a fluid having a known physical property, thereby determining whether the dispensing function of said sample dispensing apparatus is restored (claim 8) or when an abnormality of dispensing is detected during suction of a sample, discarding the sample into said cleaning bath without ejecting the sample into said reaction vessel (claims 10) or when an abnormality of sample dispensing is detected, repeatedly dispensing the relevant sample within a predetermined number of times (claims 13, 14) is not disclosed, suggested, or made obvious by the prior art of record.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P Nghiem whose telephone number is (571) 272-2277. The examiner can normally be reached on M-H.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571) 272-2269. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8000.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**MICHAEL NGHIEM  
PRIMARY EXAMINER**

Michael Nghiem

July 26, 2005